# **Exhibit D**

# UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

	)
THE COMMONWEALTH OF MASSACHUSETTS,	, ) )
Plaintiff,	) ) )
<b>v.</b>	) CIVIL ACTION NO.
MYLAN LABORATORIES, INC., BARR	) )
LABORATORIES, INC., DURAMED	)
PHARMACEUTICALS, INC., IVAX CORPORATION, WARRICK PHARMACEUTICALS CORPORATION,	<i>)</i> }
WATSON PHARMACEUTICALS, INC., SCHEIN	<i>)</i> )
PHARMACEUTICAL, INC., TEVA )	,
PHARMACEUTICAL DIG DEV DIG PETITEN	)
PHARMACEUTICAL, INC., DEY, INC., ETHEX CORPORATION, PUREPAC PHARMACEUTICAL CO.,	<i>)</i> \
and ROXANE LABORATORIES, INC.	, )
To 0.	)
Defendants.	)
·	<i>)</i> )

#### I. PRELIMINARY STATEMENT

1. Attorney General Thomas F. Reilly, on behalf of the Commonwealth of Massachusetts, brings this action against thirteen leading manufacturers of generic pharmaceutical products. This action alleges that the defendant manufacturers, over many years, by means of fraudulent promotional, marketing and sales practices, systematically and secretly have inflated the prices of generic pharmaceutical products paid for by the Massachusetts Medicaid program, resulting in millions of dollars in overpayments by the Commonwealth's taxpayers. Through these acts, each of these generic pharmaceutical manufacturers has violated the Massachusetts Medicaid False Claims Act and the Massachusetts False Claims Act and

committed common law fraud. Each of the defendant manufacturers has also violated the Medicaid Rebate Statute and breached the Medicaid Rebate Agreement through which it makes payments directly to the statesit entered into with the United States Secretary of Health and Human Services, resulting in damages to the Commonwealth of Massachusetts, an intended beneficiary of these Rebate Agreements. The Attorney General seeks injunctive relief, restitution, triple damages, civil penalties, attorneys' fees, and investigative and litigation costs.

#### II. JURISDICTION AND VENUE

2. The Attorney General of the Commonwealth of Massachusetts is authorized to bring this action pursuant to M.G.L. c. 118E, §§ 44 and 45 and M.G.L. c. 12, §§ 5B, 5G and 10. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 because the Commonwealth's claims under the Medicaid Statute and the Medicaid Rebate Agreements arise under federal law. This Court has supplemental jurisdiction over the Commonwealth's state law claims pursuant to 28 U.S.C. § 1367(a). The relief requested is authorized pursuant to M.G.L. c. 118E, § 44, M.G.L. c. 12, § 5B, 42 U.S.C. § 1396r-8 and the common law. Venue is proper pursuant to 28 U.S.C. § 1391(c).

#### III. PARTIES

#### **Plaintiff**

3. The Plaintiff Commonwealth of Massachusetts is a sovereign state and body politic duly organized by law, and is represented by the Attorney General of the Commonwealth, who brings this action in the public interest and on behalf of the Commonwealth and its citizens and taxpayers.

#### Defendants

- 4. Mylan Laboratories, Inc. ("Mylan") is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania.
- 5. Mylan is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold by Mylan and covered by Medicaid include, but are not limited to, phenytoin sodium extended, clozapine and lorazepam.
- 6. Defendant Barr Laboratories, Inc. ("Barr") is a New York corporation with its principal place of business at 2 Quaker Road, Pomona, New York. Defendant Duramed Pharmaceuticals, Inc. ("Duramed") is a Delaware corporation with its principal place of business at 7155 East Kemper Road, Cincinnati, Ohio. On information and belief, Duramed is a whollyowned subsidiary of Barr.
- 7. Barr and Duramed are in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Barr and Duramed and covered by Medicaid include, but are not limited to, warfarin sodium, methotrexate sodium, naltrexone HCl and Apri.
- 8. Defendant Ivax Corporation ("Ivax") is a Florida corporation with its principal place of business at 4400 Biscayne Boulevard, Miami, Florida. Ivax is a subsidiary of Ivax Industries, Inc., a Pennsylvania corporation with its principal place of business at Rock Plaza III, 101 Rock Road, Horsham, Pennsylvania.
- 9. Ivax is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

Pharmaceuticals that are sold manufactured by Ivax and covered by Medicaid include, but are not limited to, clozapine, albuterol and baclofen.

- Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a

  Delaware corporation with its principal place of business located at 1215 Moya Boulevard, Reno,

  Nevada. Warrick is a subsidiary of Schering-Plough Corporation, a New Jersey corporation with

  its principal place of business located in Kenilworth, New Jersey.
- 11. Warrick is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Warrick and covered by Medicaid include, but are not limited to, albuterol and albuterol sulfate.
- Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California.

  Defendant Schein Pharmaceutical, Inc. ("Schein") is a Delaware corporation with its principal place of business at 100 Campus Drive, Florham Park, New Jersey. On information and belief, Schein is a wholly-owned subsidiary of Watson.
- Watson and Schein are in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Watson and Schein and covered by Medicaid include, but are not limited to, carisoprodol, hydrocodone with APAP, ibuprofen, Necon, lorazepam, labetalol HCl, trazodone HCl and methylphenidate HCl.
- 14. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with its principal place of business at 650 Cathill Road, Sellersville, Pennsylvania.

Teva is an indirect wholly-owned subsidiary of Teva Pharmaceutical Industries Limited, a company organized under the laws of Israel with manufacturing sites in Israel, the U.S. and Europe, and an international marketing network.

- 15. Teva is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Teva and covered by Medicaid include, but are not limited to, cephalexin, clonazepam, naproxen, acetaminophen with codeine, carbamazepine, sulfamethoxazole/TMP and amiodarone HCl.
- 16. Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, New York. Par is a wholly-owned subsidiary of Pharmaceutical Resources, Inc., also a Delaware corporation with its principal place of business at One Ram Ridge Road, Spring Valley, New York.
- Par is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold manufactured by Par and covered by Medicaid include, but are not limited to, ranitidine HCl and ibuprofen.
- 18. Dey, Inc. ("Dey") is a Delaware corporation with its principal place of business at 2751 Napa Valley Corporate Drive, Napa California.
- 19. Dey is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide. Pharmaceuticals that are sold manufactured by Dey and covered by Medicaid include, but are not limited to, albuterol, albuterol sulfate, cromolyn sodium, ipratropium bromide and EpiPen.

- 20. Ethex Corporation ("Ethex") is a Delaware corporation with its principal place of business at 10888 Metro Court, St. Louis, Missouri. Ethex is a wholly-owned subsidiary of KV Pharmaceutical Company ("KV"). KV is also a Delaware corporation with its principal place of business at 2503 South Hanley Road, St. Louis, Missouri.
- 21. Ethex is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Ethex and covered by Medicaid include, but are not limited to, NitroQuick, naproxen, hyoscyamine sulfate, oxycodone HCl and potassium chloride.
- 22. Purepac Pharmaceutical Co. ("Purepac") is a Delaware corporation with its principal place of business at One Executive Drive, Fort Lee, New Jersey.
- 23. Purepac is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

  Pharmaceuticals that are sold manufactured by Purepac and covered by Medicaid include, but are not limited to, clonazepam, isosorbide mononitrate extended release and lorazepam.
- 24. Roxane Laboratories, Inc. ("Roxane") is a Delaware corporation with its principal place of business at Columbus, Ohio. On information and belief, Roxane is a subsidiary of Boehringer Ingelheim Corporation, a Nevada corporation with its principal place of business at 900 Ridgefield Road, Ridgefield, Connecticut.
- 25. Roxane is in the business of manufacturing, marketing and selling prescription pharmaceuticals that are distributed by Medicaid providers nationwide.

Pharmaceuticals that are sold manufactured by Roxane and covered by Medicaid include, but are not limited to, ipratropium bromide, Roxicodone, Roxicet, azathioprine and lithium carbonate.

#### IV. FACTS COMMON TO ALL CLAIMS

### Reimbursement for Prescription Products <u>Under the Massachusetts Medicaid Program</u>

- 26. The Massachusetts Medicaid program (the "Medicaid program") is a health care program administered by the Massachusetts Division of Medical Assistance ("DMA"), an agency of the Commonwealth of Massachusetts. The Massachusetts Medicaid program is established pursuant to 42 U.S.C. §§ 1396 et seq. (the "Medicaid Statute"). Pursuant to the Medicaid Statute and the State plan for medical assistance approved by the United States Secretary of Health and Human Services (the "Secretary") and adopted by the Commonwealth, the United States participates in the funding for the Massachusetts program in the form of grants. Fifty percent 50% of the Massachusetts Medicaid operating budget is funded by the federal government.
- 27. Among other medical goods and services, the Medicaid program pays for certain prescription drugs provided to eligible low-income individuals, including people with disabilities, children and elder citizens. The Massachusetts Medicaid program currently spends approximately \$1.2 billion annually on pharmaceutical products.
- 28. Pursuant to federal and state regulations, reimbursement to medical service providers for prescription drugs dispensed to participants in the Medicaid program is limited in accordance with formulas that are based on the provider's estimated acquisition cost of the drug or other regulatory limitations. In Massachusetts, the reimbursement rate for pharmacy providers

for multi-source drugs, including generic pharmaceuticals, is the lowest of: (a) the federal upper limit ("FULP") for the drug, if any, plus a the appropriate dispensing fee; (b) the Massachusetts upper limit ("MULP") for the drug, if any, plus a the appropriate dispensing fee; (c) the estimated acquisition cost of the drug, plus a the appropriate dispensing fee; or (d) the pharmacy's usual and customary charge for the drug. 114.3 C.M.R. 31.04. Reimbursement for single-source pharmaceutical products, which are usually brand-name drugs, or in cases where a physician has requested (and DMA has approved) the dispensing of a non-generic multi-source drug, will not exceed the lower of (a) the estimated acquisition cost of the drug plus a the appropriate dispensing fee, or (b) the usual customary charge. *Id*.

29. Massachusetts regulations promulgated by the Massachusetts Division of Health Care Finance and Policy ("DHCFP," formerly the Rate Setting Commission) and DMA define estimated acquisition cost as an estimate of the price generally and currently paid by pharmacies for the most frequently purchased package size of a particular drug. 114.3 C.M.R. 31.02; 130 C.M.R. 406.402. Before August 3, 2002, estimated acquisition cost was further defined by Massachusetts regulation as the drug wholesaler's acquisition cost ("WAC") plus 10%. 114.3 C.M.R. 31.02. Effective August 3, 2002, estimated acquisition cost is defined as WAC plus 6%. *Id*.

### The Defendant Manufacturers' Price Reporting Mechanisms

30. Each defendant provides to the Commonwealth, both directly and through submission of reports to drug pricing publishing services indirectly, what purports to be genuine pricing data for its products. Each defendant also periodically submits such pricing data to various national drug pricing publishing services This information is typically identified as the

"Wholesale Acquisition Cost" ("WAC") and/or the "Average Wholesale Price" ("AWP") of particular products. The defendant manufacturers intend the WAC to be understood by the state Medicaid agencies as the average price paid by a wholesaler to a manufacturer for a given product. The defendant manufacturers intend the AWP to be understood by the state Medicaid agencies as the average price charged by a drug wholesaler to its commercial customers for a given product. The drug pricing publishing services in turn compile, publish and distribute compendia of such pricing information for each defendant's products. The drug pricing publishing services purport not to investigate the accuracy of the information provided by the manufacturers, and disclaim responsibility for its accuracy.

- 31. At all times relevant to this action, each of the defendant manufacturers provided information on WAC prices for prescription drugs, or other drug pricing information, to First Data Bank ("FDB"), a data reporting service with its headquarters located in San Bruno, California.
- 32. Each of the defendants affirmatively endeavors to conceal maintain the confidentiality of the actual prices it charges its customers. On information and belief, each of the defendants this includes the uses of undisclosed discounts, rebates and other inducements pricing mechanisms that have the effect of lowering the actual price charged to its the customers. As a result of these concealed inducements, each defendant has prevented and of making it difficult, if not impossible, for third parties, including the Commonwealth, from to determineing independently the true prices it charged its customers. At all times relevant to this action, each of the defendant manufacturers knew that information accurately reflecting the actual sales prices it charged its customers was not available to the state Medicaid agencies.

- Each defendant intended that the pricing information that provided to the Commonwealth, both directly and indirectly through the data reporting services, would be used by the Commonwealth to in determineing the reimbursement levels to be paid by the Massachusetts Medicaid program for that defendant's products.
- 34. At all times relevant to this cause of action, each of the defendant manufacturers provided information on WAC prices for prescription drugs, and other drug pricing information, to First Data Bank ("FDB"), a data reporting service with its headquarters located in San Bruno, California. At all times relevant to this action, neither DMA nor DHCFP knew the actual prices each of the defendants charged its customers for its products. Rather, DMA obtained pricing this information from FDB, and DMA and DHCFP reasonably relied did in fact rely on this information in determining the Medicaid reimbursement levels for the products of each of the defendant manufacturers.

#### The Medicaid Rebate Program

35. Under the Omnibus Budget Reconciliation Act of 1990, Congress established a Medicaid Drug Rebate Program (the "Medicaid rebate program"). 42 U.S.C. § 1396r-8 (the "Rebate Statute"). The Medicaid rebate program provides that, in order for a manufacturer's drugs to be eligible for reimbursement under Medicaid, the manufacturer is required to enter into a national Medicaid Rebate Agreement ("Rebate Agreement"). 42 U.S.C. § 1396r-8(a)(1). The Medicaid rebate program is administered by the federal Center for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), for the benefit of the federal and state governments.

- 36. Under a Rebate Agreement, the manufacturer of a generic drug is required to pay a rebate to each state in an amount equal to 11% of the Average Manufacturer Price ("AMP") of each unit of the generic drug for which the state Medicaid program paid reimbursement. 42 U.S.C. § 1396r-8(c)(3). The AMP for a given drug, which is required to be reported to the Secretary by the manufacturer, is defined by statute as the average price paid to the manufacturer in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts, and must therefore reflect any other discounts, free goods, rebates and other inducements that have the effect of lowering the actual net price paid by customers to the manufacturer. 42 U.S.C. § 1396r-8 (k)(1).
- 37. The express and essential purpose of the Medicaid rebate program is to give the state Medicaid programs the benefit of the best price at which the manufacturer sells the drug to any public or private purchaser.
- 38. Pursuant to the Rebate Agreement and the Rebate Statute, these AMPs are not reported to the states. See 42 U.S.C. § 1396r-8(b)(3)(A). Rather, each of the defendant manufacturers provides these AMPs to CMS., and CMS relies on the data provided by each of the defendant manufacturers to then calculates the quarterly rebate amount for each unit of the defendants' covered drugs (, the "Unit Rebate Amount" or "URA."). CMS provides the URAs for each covered drug to the state Medicaid agencies on a quarterly basis., but does not provide AMP information to the states.
- 39. Under each manufacturer's Rebate Agreement and the Rebate Statute, both the Secretary and the state Medicaid agencies are required to keep confidential any pricing

information disclosed by manufacturers or wholesalers in connection with their participation in the rebate program. See 42 U.S.C. § 1396r-8(b)(3)(D).

40. The Commonwealth of Massachusetts relies on the manufacturers' performance under the Rebate Agreements to obtain accurate provide the appropriate URAs for covered drugs, and uses the information provided by CMS pursuant to the Rebate Agreements to calculate and submit as the basis for the rebate invoices submitted on a quarterly basis by DMA to each of the defendant manufacturers.

The express and essential purpose of the rebate program is to give the state

Medicaid programs the benefit of the best price at which the manufacturer sells the drug to any

public or private purchaser. 1. Each defendant in this action has entered into a Rebate Agreement,

and the products of each defendant are, as a result, eligible for reimbursement by the

Commonwealth's Medicaid program. Each defendant participates in the Medicaid Rebate

Program and is subject to all the legal duties imposed upon it pursuant to the statutory and

regulatory authority governing the Medicaid Rebate Program.

41. The Commonwealth of Massachusetts relied on the benefits conferred by the Medicaid Rebate program, and on the performance by each of the defendant manufacturers of the obligations imposed by the Rebate Agreements, to ensure that the Massachusetts Medicaid program paid the best price available for the pharmaceutical products of each of the defendants.

### The Defendants' Reported WACs and AWPs Were False and Fraudulent

42. On information and belief, the WAC and AWP prices reported by each of the defendants directly and indirectly to the Commonwealth do not reflect, and have no correlation to, the actual prices charged to customers for pharmaceutical

products in the market. Rather, these reported WAC and AWP prices are materially inflated.

- 43. As a direct result of these false and inflated reports of WACs and AWPs, the Massachusetts Medicaid program paid pharmacy providers excessive amounts for pharmaceutical products.
- 44. At all times relevant to this action, each of the defendant manufacturers knew that the published WACs and AWPs for its products failed to reflect accurately the actual sales prices paid by its customers.
- 45. At all times relevant to this action, each of the defendant manufacturers knew that the Medicaid reimbursement levels for its products were based upon these improperly inflated WACs and AWPs.
- 46. In falsely and fraudulently inflating its reported prices, each defendant knowingly and intentionally subverted the Medicaid provider cost-reimbursement system so that each defendant caused the Medicaid reimbursement to materially exceed the providers' acquisition cost of that defendant's drugs.
- 47. The intention of each of the defendant manufacturers in providing false and misleading pricing information for publication was to create a "spread" between the published prices for its products, upon which government reimbursement rates are based, and the actual prices paid by its customers. The purpose of each defendant in creating the "spread" was to provide incentives or "kickbacks" for customers who buy and distribute its products, to increase the profits for such customers at the expense of the state Medicaid programs, and to increase its own profits by increasing its market share for particular drugs and classes of drugs.

- 48. On information and belief, nNotwithstanding the pricing data that each defendant provided directly and indirectly to the Commonwealth, each defendant reported to HCFA or CMS, on a quarterly basis, AMPs that were materially lower than its reported WACs and AWPs, and these lower AMPs were used by HCFA or CMS in determining the URAs upon which each defendant's rebates to the state Medicaid programs were based.
- The price manipulation schemes of each defendant occurred throughout the period relevant to the Ccomplaint and beginning at least as early as 1994. Exhibits A through K to theis complaint set forth the following quarterly data for each of the subject drugs of each defendant: (a) the specific Medicaid unit reimbursement amount; (b) the total number of units for which the Massachusetts Medicaid program paid reimbursement; (c) and the total amount reimbursed by the Massachusetts Medicaid program. The Exhibits Attachments also include a column in which the Commonwealth is prepared to set forth an approximation of the AMPs reported to CMS or HCFA by each defendant for each of its subject drugs. In light of the confidentiality requirements of the Medicaid rebate statute and the potential competitive sensitivity of such pricing information, the AMP column has been left blank. With the filing of theis Ccomplaint, the Commonwealth has moved for leave to file with the Court Exhibits AA through KK, which that consist of Exhibits A through K with the AMP information included. In addition, with the service of the Ccomplaint, each defendant will be provided with a copy of that portion of Exhibits AA through KK pertaining solely to its products.
- 50. On information and belief, and aAs reflected in Attachments AA through KK, the AMPs reported by each defendant manufacturer to CMS for each of the subject

drugs are materially lower for multiple quarters than the Medicaid reimbursement amounts for those products.

#### COUNT I Fraud

- 51. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through fifty-one (1-51) above, as if they were fully set forth here.
- 52. Each of the defendants knew that its promotional, marketing and sales practices employed false and misleading pricing information provided to the national drug price reporting services.
- 53. Each of the defendants intended to induce the Commonwealth of Massachusetts, through DMA and the DHCFP, to rely upon the statements and representations contained in this false and misleading pricing information.
- 54. The Commonwealth did in fact reasonably rely upon the statements and representations contained in this false and misleading pricing information.
- 55. As a result of its reasonable reliance upon the statements and representations contained in this false and misleading pricing information, the Commonwealth of Massachusetts paid its Medicaid pharmacy providers sums in excess of the amounts to which the providers were entitled.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

### COUNT II Unjust Enrichment

- 56. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through fifty-six (1-56) above, as if they were fully set forth here.
- 57. As a result of the statements and representations contained in each defendant's false and misleading pricing information, the Commonwealth of Massachusetts paid its Medicaid pharmacy providers sums in excess of the amounts to which the providers were entitled.
- 58. Each defendant knew that the Commonwealth's Medicaid providers were not entitled to these improperly inflated reimbursements.
- 59. As a result of the Commonwealth's excessive payments to its Medicaid pharmacy providers, each of the defendants obtained increased sales and market share and was unjustly enriched at the expense of the Commonwealth of Massachusetts.
- 60. Each defendant knew that it was not entitled to the profits it realized from the increased sales and increased market share that resulted from the Commonwealth's excessive payments to its Medicaid pharmacy providers.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

Violations of the Massachusetts Medicaid False Claims Act
(M.G.L. c. 118E, §§ 40 and 41)

- 61. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through sixty-one (1-61) above, as if they were fully set forth here.
- 62. Each of the defendants produces, markets and sells pharmaceutical products for which DMA makes payment.
- 63. Each of the defendants knowingly and wilfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to DMA, to obtain reimbursement for Medicaid providers for its pharmaceutical products, in violation of M.G.L. c. 118E, § 40.
- 64. Each of the defendants uses devices and schemes that have the effect of increasing the total amount claimed or paid for its pharmaceutical products and services beyond the maximum allowable amount payable for such products and services under the applicable rate or fee schedule, in violation of M.G.L. c. 118E, § 40.
- 65. The failure of each of the defendants to disclose to governmental entities or to the drug pricing reporting services the marketing, promotional and pricing inducements it offers to its purchasers, and the failure of each of the defendants to report the net reduction in the prices paid by the purchasers of its products caused by these inducements, constitute violations of M.G.L. c. 118E, § 40.
- other price-based incentives to its customers, with the intention that these inducements increase the profits for such purchasers at the expense of the Massachusetts Medicaid program, constitutes an illegal kickback in violation of M.G.L. c. 118E, § 41.

- 67. The conduct of each of the defendants in manipulating reimbursement levels so as to preclude the Massachusetts Medicaid program from benefitting from these inducements, constitutes the provision of an illegal kickback in violation of M.G.L. c. 118E, § 41.
- 68. As a result of these false statements and/or representations of material facts by each of the defendants, DMA has paid sums in excess of the amounts that should have been paid to Medicaid providers for pharmaceutical products.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

# COUNT IV Violations of the Massachusetts False Claims Act (M.G.L. c. 12, §§ 5A et seq.)

- 69. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through sixty-nine (1-69) above, as if they were fully set forth here.
- 70. Each of the defendants produces, markets and sells pharmaceutical products for which DMA makes payment.
- 71. Each of the defendants knowingly and wilfully made or caused to be made false statements and/or representations of material facts, directly and indirectly to DMA, to obtain reimbursement for Medicaid providers for its pharmaceutical products, in violation of M.G.L. c. 12, §§ 5A et seq.
- 72. Each of the defendants uses devices and schemes that have the effect of increasing the total amount claimed or paid for pharmaceutical products and services beyond the

maximum allowable amount payable for such products and services under the applicable rate or fee schedule, in violation of M.G.L. c. 12, §§ 5A et seq.

- 73. The failure of each of the defendants to disclose to governmental entities or to the drug pricing reporting services the marketing, promotional and pricing inducements it offers to its purchasers, and the failure of each of the defendants to report the net reduction in the prices paid by the purchasers of its products caused by these inducements, constitute violations of M.G.L. c. 12, §§ 5 et seq.
- 74. As a result of these false statements and/or representations of material facts by each of the defendants, DMA has paid sums in excess of the amounts which should have been charged for pharmaceutical products.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

### COUNT V Breach of Contract

- 75. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through seventy-five (1-75) above, as if they were fully set forth here.
- 76. Pursuant to 42 U.S.C. § 1396r-8, each of the defendants has entered into a Rebate Agreement, under which each defendant agreed to provide to CMS (formerly HCFA) periodic reports of true and accurate pricing information concerning sales of its pharmaceutical products in the form of an AMP as defined in the Rebate Statute and to pay the Commonwealth a rebate in the amount of 11% of the AMP for each unit of its covered drugs reimbursed by the Commonwealth under the Medicaid program.

- 77. The Commonwealth of Massachusetts is an intended third-party beneficiary of the Rebate Agreements entered into by each of the defendants.
- 78. Based on the pricing information that each defendant provided to the Commonwealth, both directly and indirectly through national pricing data reporting services, the AMPs reported by each defendant for purposes of calculating the rebates due under the Rebate Agreements were materially understated.
- 79. In materially understating its AMPs, each defendant has breached its Rebate Agreement with the federal government.
- 80. Each defendant, as a result of its failure to comply with its obligations under its Rebate Agreement, has deprived the Commonwealth of Massachusetts of the appropriate level of rebates for covered pharmaceutical products as provided in the Rebate Agreements and as mandated by 42 U.S.C. § 1396r-8.
- The Commonwealth has been damaged in an amount equal to the difference between the rebates that should have been paid and the rebates actually paid by each defendant.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

### COUNT VI Breach of Duty of Good Faith and Fair Dealing

82. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through eighty-two (1-82) above, as if they were fully set forth here.

- 83. Pursuant to 42 U.S.C. § 1396r-8, each defendant has entered into a Rebate Agreement, under which it agreed to pay the Commonwealth a rebate in the amount of 11% of the AMP for each unit of its covered drugs reimbursed by the Commonwealth under its Medicaid program.
- 84. The Commonwealth of Massachusetts is an intended third-party beneficiary of the Rebate Agreements entered into by each of the defendants.
- 85. The essential purpose and intent of the Rebate Agreements is to ensure that the state Medicaid programs pay the lowest price available in the market for the participating manufacturers' pharmaceutical products.
- 86. Notwithstanding each defendant's obligations under its Rebate Agreement to pay rebates to the Commonwealth in such amounts as will cause the Medicaid program to pay the lowest price available in the market for the participating manufacturers' pharmaceutical products, each defendant has deprived the Commonwealth of any benefit of the Rebate Agreement by reporting false and inflated pricing data for its drugs. These reports of false and inflated pricing information caused the reimbursement rates for each defendant's drugs to be artificially inflated in amounts materially in excess of any rebates paid under that manufacturer's Rebate Agreement. Each defendant has thereby frustrated the fundamental purpose and intent of its Rebate Agreement and deprived the Commonwealth of the benefits of that Agreement.
- 87. In so doing, each defendant has breached its duty of good faith and fair dealing implicit in its Rebate Agreement, with the federal government and the Commonwealth has been damaged in the amount that it was caused to overpay for each defendant's drugs.

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

### COUNT VII Violation of 42 U.S.C. § 1396r-8

- 88. The Commonwealth of Massachusetts hereby repeats, realleges and incorporates by reference the facts as contained in paragraphs one through eighty-eight (1-88) above, as if they were fully set forth here.
- 89. Each of the defendant manufacturers has failed to provide accurate pricing information as required by 42 U.S.C. § 1396r-8 (b)(3).
- 90. As a result, each of the defendant manufacturers has failed to pay the appropriate amount of rebates to the Commonwealth of Massachusetts as required by 42 U.S.C. § 1396r-8 (c)(3).

WHEREFORE, the Commonwealth of Massachusetts demands judgment against each of the defendants as prayed for below.

#### PRAYER FOR RELIEF

Based on the foregoing, the Commonwealth of Massachusetts respectfully demands judgment as follows:

- A. An order of this Honorable Court enjoining each of the defendants from engaging in practices that violate M.G.L. c. 118E, §§ 40 and 41, M.G.L. c. 12, §§ 5 et seq., 42 U.S.C. § 1396r-8 and their obligations under the Medicaid Rebate Agreement;
  - B. Damages in such amount as is proved at trial;
  - C. Damages trebled pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
  - D. Disgorgement of all excessive profits in such amount as is proved at trial;

- E. Civil penalties pursuant to M.G.L. c. 12, § 5B;
- F. Reimbursement for all investigative and litigation costs, including experts' fees, pursuant to M.G.L. c. 118E, § 44 and M.G.L. c. 12, § 5B;
  - G. An award of attorneys' fees pursuant to M.G.L. c. 12, § 5B; and
  - H. Such other and further relief as this Honorable Court deems proper and just.

#### **JURY DEMAND**

The Commonwealth of Massachusetts demands trial by jury on all claims so triable.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS By its attorney,

THOMAS F. REILLY Attorney General

By:

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September , 2003

### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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	) )
THE COMMONWEALTH OF MASSACHUSETTS,	)
	)
Plaintiff,	3 1 1865 PBS
(	13 1 1 8 0 5 1 1 2 2
v.	CIVIL ACTION NO.
	)
MYLAN LABORATORIES, INC., BARR	)
LABORATORIES, INC., DURAMED	)
PHARMACEUTICALS, INC., IVAX CORPORATION,	)
WARRICK PHARMACEUTICALS CORPORATION,	)
WATSON PHARMACEUTICALS, INC., SCHEIN	)
PHARMACEUTICAL, INC., TEVA	)
PHARMACEUTICALS USA, INC., PAR	<u>,</u>
PHARMACEUTICAL, INC., DEY, INC., ETHEX	)
CORPORATION, PUREPAC PHARMACEUTICAL CO.,	)
and ROXANE LABORATORIES, INC.	, )
	)
Defendants.	ĺ
DOMINATE.	, )
	)
	<i>)</i>

## COMMONWEALTH'S MOTION FOR LEAVE TO FILE EXHIBITS

The Commonwealth of Massachusetts respectfully moves this Honorable Court for leave to file Exhibits AA through KK to its Complaint. These exhibits are the same as Exhibits A through K but with the Calculated Average Manufacturer Price filled in. As reasons for its motion, the Commonwealth states as follows:

The Commonwealth alleges in its complaint that the defendant pharmaceutical manufacturers have, from at least 1994 to the present, engaged in fraudulent promotional, marketing and sales practices in order to inflate the prices of generic pharmaceutical products

### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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THE COMMONDUE ALTER OF MARCA CHRISTOPPE	<del>\</del>	
THE COMMONWEALTH OF MASSACHUSETTS,	)	
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Plaintiff,	03011805	NOO
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v.	) CIVIL ACTION NO.	
	)	
MYLAN LABORATORIES, INC., BARR	)	
LABORATORIES, INC., DURAMED	)	
PHARMACEUTICALS, INC., IVAX CORPORATION	۷, ´)	
WARRICK PHARMACEUTICALS CORPORATION,		
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CORPORATION, PUREPAC PHARMACEUTICAL C	ro í	
and ROXANE LABORATORIES, INC.	)	
and the state of t	<u>'</u>	
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	)	

## COMMONWEALTH'S MOTION FOR LEAVE TO FILE EXHIBITS

The Commonwealth of Massachusetts respectfully moves this Honorable Court for leave to file Exhibits AA through KK to its Complaint. These exhibits are the same as Exhibits A through K but with the Calculated Average Manufacturer Price filled in. As reasons for its motion, the Commonwealth states as follows:

The Commonwealth alleges in its complaint that the defendant pharmaceutical manufacturers have, from at least 1994 to the present, engaged in fraudulent promotional, marketing and sales practices in order to inflate the prices of generic pharmaceutical products

paid for by the Massachusetts Medicaid program, and that these practices have resulted in millions of dollars in overpayments by the Commonwealth. Part of the proof of the Commonwealth's allegations with respect to damages involves a demonstration of the difference between these inflated Medicaid reimbursement levels and the actual market price of numerous drugs sold by the defendants.

Paragraph 50 of the complaint states:

The price manipulation schemes of each defendant occurred throughout the period relevant to the complaint and beginning at least as early as 1994. Exhibits A through K to the complaint set forth the following quarterly data for each of the subject drugs of each defendant: (a) the specific Medicaid unit reimbursement amount; (b) the total number of units for which the Massachusetts Medicaid program paid reimbursement; (c) and the total amount reimbursed by the Massachusetts Medicaid program. The Exhibits also include a column in which the Commonwealth is prepared to set forth an approximation of the AMPs [Average Manufacturers Prices] reported to CMS [the Center for Medicare and Medicaid Services] or HCFA [the Health Care Financing Administration] by each defendant for each of its subject drugs. In light of the confidentiality requirements of the Medicaid rebate statute, the AMP column has been left blank. With the filing of the complaint, the Commonwealth has moved for leave to file with the Court Exhibits AA through KK, which consist of Exhibits A through K with the AMP information included. In addition, with the service of the complaint, each defendant will be provided with a copy of that portion of Exhibits AA through KK pertaining solely to its products.

(emphasis added).

While the Commonwealth believes that any such pricing information, except possibly that relating to the most recent quarter, could not be considered confidential or proprietary, one or more of the defendants may take the position that the Commonwealth's calculated approximation of the AMPs of the defendants' products constitutes a disclosure of confidential information prohibited by 42 U.S.C. § 1396r-8(b)(3)(D), and may therefore object to the filing of a public document containing this information. Accordingly, the Commonwealth submits this

motion before filing Exhibits AA through KK in order to apprise the Court of this issue, to permit the defendants to raise any such objection, and enable the parties to deal with the issue pursuant to the instructions of the Court.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS By its attorney,

THOMAS F. REILLY Attorney General

By:

David S. Nalven (BBO# 547220)
Nicholas J. Messuri (BBO# 547144)
Robert Patten (BBO# 555287)
Richard C. Heidlage (BBO# 228940)
Assistant Attorneys General
200 Portland Street
Boston, MA 02114
(617) 727-2200

September 25, 2003

#### CERTIFICATE OF SERVICE

As set forth in the Complaint, service of the foregoing document will be made upon each detendant by including a copy with the Complaint when it is served.

Richard C. Heidlage